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DWIGHT DAVID EISENHOWER ARMY MEDICAL CENTER FORT BOR--ETC F/G 6/5
ANNUAL RESEARCH PROGRESS REPORT, FISCAL YEAR 1980, (U)
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DEPARTMENT OF CLINICAL INVESTIGATION
DWIGHT DAVID EISENHOWER
ARMY MEDICAL CENTER
FT. GORDON, GEORGIA 30905

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19. KEY WORDS (Continue on reverse side if necessary and identify by block number) Unit Summary; Detail Sheet (Study Objective, Technical Approach, Progress, Status); Publications; Presentations.		
20. ABSTRACT (Continue on reverse side if necessary and identify by block number) Subject report identifies the research activities conducted by Dwight David Eisenhower Army Medical Center investigators through protocols approved by the Institutional Review Committee for registration with the Department of Clinical Investigation during Fiscal Year 1980, and other known publications and pre- sentations by the Dwight David Eisenhower Army Medical Center professional staff. A detail sheet of each protocol giving the objective, technical approach and progress is presented.		

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FORWARD

The year just ended, FY 80, was a year of change for the Clinical Investigation program at the Dwight David Eisenhower Army Medical Center. It was a year in which overall management of the program was assumed by a committee of directors, a year in which the Assistant Chief retired, a year during which we achieved full departmental status, a year during which additional space was authorized for expansion, and finally a year towards the end of which a new department chief was named.

It is a tribute to the staff of this department and DDEAMC that throughout the year and despite the changes which occurred, they continued their productive efforts, undaunted, with 23 publications in professional journals and 45 presentations. During this same period 9 protocols were completed and 29 were terminated. I would like to take this opportunity to thank the full staff for their support and total dedication to the fulfillment of our research mission.

The continued support of BG Frederick C. Biehuse, DDEAMC Commander, and his professional and administrative staff is appreciated, and promises to lead to still greater productivity for this department in the succeeding years. A special word of appreciation is due COL James W. Reed (recently retired) who, as Chairman of our Directorate, served our needs most conscientiously despite his very busy schedule as Chief, Department of Medicine.

The retirement of LTC Andree J. Lloyd in June 1980 was most disappointing. It is his efforts in daily management as Assistant Chief that are most responsible for the efficient manner in which the work represented by this report was accomplished.

I would especially like to acknowledge the total dedication of Ms. Rosina Martinez, the editorial assistant for the Department of Clinical Investigation. Her coordination of protocol development, manuscript preparation and review, meeting coordination, and liaison with the Clinical Investigation Program Division at Health Services Command could not have been performed more appropriately.

The research represented by the contents of this annual report was conducted in accordance with AR 40-38, as amended, "Clinical Investigation Program"; AR 40-7, "Use of Investigational Drugs in Humans"; AR 70-25, "Use of Volunteers as Subjects for Research"; and HSC Reg 40-23, "Management of Clinical Investigation Protocols and Reports". Also, AR 70-18, "Laboratory Animals, Procurement, Transportation, Use, Care, and Public Affairs" governed the animal use studies.

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Jack A. Horner

JACK A. HORNER, DAC
Assistant Chief
Department of Clinical Investigation

UNIT SUMMARY - FISCAL YEAR 1980

A. Objectives.

The objectives of the Department of Clinical Investigation, DDEAMC, are threefold:

- 1) to provide a facility and atmosphere conducive to the pursuit of basic and applied medical research by the staff of DDEAMC;
- 2) to provide training and experience programs in research related areas for residents and staff; and
- 3) the maintenance and supply of animals as needed and approved for DDEAMC elements.

The Department of Clinical Investigation is administratively aligned under the Chief, Professional Services. During FY 80 the department was operated under the guidance of the Clinical Investigation Directorate composed of Chiefs of the Departments of Medicine, Surgery, Psychiatry and Neurology, Pathology, and Family Practice.

B. Technical Approach.

All research, investigational, and training activities within the Department of Clinical Investigation are conducted under the guidance of AR 40-38, AR 40-7, AR 70-25, AR 70-18, and HSC Reg 40-23. Careful monitoring of all approved protocols is conducted in order to assure strict compliance with these applicable regulations.

C. Staffing.

<u>Name</u>	<u>Rank</u>	<u>MOS</u>	<u>Title</u>
			Chief
Lloyd, Andree J.*	LTC	68T9B	Res Psychologist
Arensman, John B.	MAJ	64A00	Veterinarian
Hannan, Charles J., Jr.	CPT	68Z00	Physiologist
Harris, Richard W.	CPT	68J00	Microbiologist
	E6	92B20	NCOIC
Jones, Frederick Jr.	SSG	92T20	Sen Animal Sp, Act'g NCOIC
Lohr, Edward M.	SP5	92D10	Chem Lab Sp
Blanco, Diana T.	SP5	01H20	Biological Science Asst
Lohr, Patricia S.	SP4	92T10	Animal Sp
Crawford, Nettie L.	SP4	74F10	Programmer/Analyst
Horner, Jack A.**	GS13	01301	S Res Histologist
McPherson, James C. III, PhD	GS11	01320	Biochemist
Patterson, Robert A.	GS9	00181	Psychology Technician
	GS9		Medical Technologist
	GS7		Medical Technician
Martinez, Rosina	GS6	01087	Editorial Assistant
Stapleton, Agnes	GS3	00322	Clerk Typist (Temporary)
Silas, Bill E.	WG5	07706	Animal Caretaker

*Acting Chief October 1979-June 1980

**Acting Chief July-September 1980

Clinical Investigation Directorate

COL James W. Reed, MC, Chief, Department of Medicine, Chairman
COL K. Eric Nelson, MC, Chief, Professional Services
COL George K. Powell, MC, Chief, Department of Surgery
COL Ronny J. Sayers, MC, Chief, Department of Pathology
COL William G. Caput, MC, Chief, Department of Family Practice

D. Funding.

Type	Fiscal Year 79	Fiscal Year 80
Civilian personnel to include benefits	105,323.90	116,417.00
Consumable supplies	80,962.94	73,176.00
Civilian contracts to include consultants	4,300.00	1,600.00
TDY	3,711.00	5,266.00
Publications	490.34	944.00
Noninvestment equipment (Minor MEDCASE)		325.00
Other OMA		20,287.00
OMA Total	3,805.82	20,612.00
MEDCASE	83,222.00	50,767.00
Other	3,685.00	2,979.00
Military	151,098.00	85,959.00
Total	436,596.00	378,332.00

E. Progress.

Protocol Disposition FY 80

	<u>Completed</u>	<u>Terminated</u>	<u>Ongoing to FY 81</u>
FY 78	-	24	6
FY 79	1	3	15
FY 80	8	2	23
	<u>9</u>	<u>29</u>	<u>44</u>

F. Problems.

The Department of Clinical Investigation at DDEAMC is experiencing a number of problems, none of which is unique, but which, taken as a whole, are having significant impact on full implementation of our mission. The department is located in a portion of what remains of the old Fort Gordon Army Hospital, temporary buildings erected during World War II. The building is uninsulated, overcrowded, in poor repair, and by nature of its construction represents a major fire and safety hazard. Additionally, the location is distant to the hospital which is a significant hindrance to collaborative research, particularly with busy staff who find little available time for research. The only solution to this problem is construction of a new facility adjacent to the main hospital, a project which we understand is currently in an unprogrammed year more than seven years away.

Similarly, much of the equipment within the department was obtained over the years by lateral transfer from surplus lists. This equipment was old when received and is even older now. There is an urgent need for major equipment replacement. MEDCASE monies should be best used for expansion of technical capabilities, but instead are having to be applied toward replacement items. Special monies need to be made available.

There is an ever present need for personnel, particularly technical support personnel. The delays encountered in obtaining fills of enlisted vacancies is excessive. As an example we have been without an NCOIC for over a year due to the shortage of MOS 92B personnel. Every effort should be made to identify and prioritize personnel needs and expedite assignments. A similar problem exists when good, well trained, and experienced personnel receive orders for reassignment. Some clear cut mechanism for stabilization should be formulated in order that better continuity of research can be had.

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Code:

O - Ongoing
C - Completed
T - Terminated

P - Published
PR - Presented
SP - Submitted for Publication

PUBLICATIONS FY 80

DEPARTMENT OF CLINICAL INVESTIGATION

- Hannan, C.J. and Lloyd, A.J.: Characteristics of the Interresponse Time of the Mongolian Gerbil. Bull Psychonomic Soc, 14:260, 1979. (C)
- Patterson, R.A. and Hannan, C.J.: Learned Helplessness in the Gerbil. Georgia J Sci, 38(2):115, Apr 1980. (C)
- Cowan, G.S.M. and McPherson, J.C. III: Insulin Kinetics With IV Hyperalimentation (IVH) in Polyvinylchloride (PVC) and Glass Containers. Georgia J Sci, 38(2):120, Apr 1980. (C)
- Blanco, D.T. and McPherson, J.C. III: Effect of Dose and Length of Steroid Administration on Serum Gonadotropins and Secondary Sex Organs in Immature Male Rats. Georgia J Sci, 38(2):116, Apr 1980. (C)
- McPherson, J.C. III: Anatomy of a Rat With a Congenital Anomaly of the Reproductive System. Georgia J Sci, 38(2):122, Apr 1980. (C)
- Hannan, C.J.: New Gerbil Model Stroke. Soc Neurosci, 6:827, 1980. (C)
- Priest, G. and Horner, J.A.: Fibrous Ceramic Aluminum Silicate as an Alternative to Asbestos Liners. J Prost Dent, 44(1):51-56, Jul 1980. (C)
- McPherson, J.C. III, McPherson, J.C. Jr., Berdanier, C.D.: Voluntary Food Consumption, Gastric Emptying and Intravenous Non-Ionic Surface-Active Agents (NISAA) in Rats. Federation Proc, 39:305, 1980. (C)
- Cowan, G.S.M. and Horner, J.A.: Direct Grounding Tool for Examination of Uncoated Specimens in the Scanning Electron Microscope. Rev Sci Instr, 50(10):1314, Oct 1979. (C)
- McPherson, J.C. III and Mahesh, V.B.: Divergent Patterns of FSH and LSH Induced by 17 -Hydroxyprogesterone and Progesterone Metabolites in the Estrogen Primed Castrated Rat. Endocrine Soc Prog & Abs, Abs #762, p. 265, Jun 1980. (C)
- Grier, H.A., Horner, J.A., Mahesh, V.B.: The Morphology of Enclosed Testicular Tubules in a Teleost Fish, Poecilia Latipinna. Trans Amer Micros Soc, 99(3): 268-276, 1980.

DEPARTMENT OF MEDICINE

- Haburchak, D.R. and Moore, W.L.: Rickettsial Disease, in Current Diagnosis, Conn & Conn, Ed. W.B. Saunders, Philadelphia, 1980, p. 141.
- Reed, J.W. and McCowen, K.D.: Hyperthyroidism and Thyroid Cancer. Postgraduate Med, 67:169, Feb 1980.
- Rissing, J.P., Newman, D., Crockett, J., Buxton, T.B., Moore W.L. Jr., Edmonson, H.T.: Metronidazole in the Treatment of Anaerobic Infections. Current Therapeutic Res, 27(5):651-663, 1980.

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Burgess, R.E., Burgess, V.F., Dibella, N.J.: Brain Metastases in Small Cell Carcinoma of the Lung. JAMA, 242(19):2084-2086, Nov 1979.

Tenholder, M.F., Jones, P.A., Matthews, J.I.: Bullous Emphysema - Progressive Incremental Exercise Testing to Evaluate Candidates for Bullectomy. Chest, 77: 802-805, Jun 1980.

Tenholder, M.F. and Hooper, R.G.: Pulmonary Infiltrates in Leukemia. Chest, 78:468-473, Sep 1980.

ACCEPTED

Moore, W.L., Jr.: History of the United States Army Medical Department in the Republic of Vietnam. Melioidosis (In Press)

Moore, W.L., Jr.: Glanders; Melioidosis. In The Science and Practice of Clinical Medicine. Grune & Stratton, Inc., New York. (In Press)

Haburchak, D.R., Michaels, G., Hernandez, I., Wolfe, H.: Acute Respiratory Disease, Fort Gordon, GA. Accepted by Military Medicine.

Haburchak, D.R.: Sporadic Military Meningococcal Disease - A Diversity of Presentations. Accepted by Southern Med J.

SUBMITTED

Blake, G.H., Haburchak, D.R.: Cervicofacial Actinomycosis Associated With Eikenella Corrodens. Submitted to Arch Int Med.

DEPARTMENT OF PSYCHIATRY AND NEUROLOGY

Guyden, T.E., Frenkel, S.I., Greden, J.F., et al: Does Patient Contact Change Racial Perceptions? J Amer Nurs, 80(7):1340-1342, Jul 1980.

Zingale, S.A., Smith, M.D., DeKecki, P.R.: Temporal Stability of the Metropolitan Achievement Test When Used With Learning Disabled Children. Learning Disabilities Quarterly, 3(2):84-86, 1980.

ACCEPTED

Bank R.L., Georgoulakis, J., Jenkins, J.A.: Counseling Intervention In Basic Combat Training. Accepted by Mil Med (In Press).

DEPARTMENT OF PATHOLOGY

Boe, G.P.: Transactional Analysis: A Basic Tool for Understanding Relationships. Med Lab Obs, Oct 1979.

Boe, G.P.: A Systems Approach to Evaluation of Programs in Vocational-Technical Training. J Amer Med Technol, pp. 17-19, Jan-Feb 1980.

Boe, G.P.: Unity is Dividing Us. Lab World, Jun 1980.

PUBLICATIONS

ACCEPTED

Boe, G.P.: Autoimmune Disease. Accepted by J Amer Med Technol, Nov-Dec 1980.
(In Press)

SUBMITTED

Boe, G.P. and Ponder, L.D.: Blood Donors and Non-Donors - A Review of the Research.
Submitted to J Amer Med Technol.

Boe, G.P.: How to Deal With Stress in the Laboratory. Submitted to Med Lab Obs.

DEPARTMENT OF NURSING

Umphenour, J.H.: Bacterial Colonization in Neonates With Sibling Visitation.
JOGN Nursing, 9(2):73-75, Mar-Apr 1980.

ACCEPTED

Renaud, M.: Parental Response to Family Centered Maternity Care. Accepted by
Mil Med.

PRESENTATIONS FY 80

DEPARTMENT OF CLINICAL INVESTIGATION

McPherson, J.C. III: Voluntary Food Consumption, Gastric Emptying and Intravenous Non-Ionic Surface-Active Agents (NISAA) in Rats. Federation Amer Soc Experi Biol, Anaheim, CA, Apr 1980. (C)

Blanco, D.T. and McPherson, J.C. III: The Effect of Dose and Length of Steroid Administration on Serum Gonadotropins and Secondary Sex Organs in Immature Rats. Georgia Academy Sci, Macon, GA, Apr 1980. (C)

McPherson, J.C. III and Mahesh, V.B.: Divergent Patterns of FSH and LH Induced by 17 -Hydroxyprogesterone and Progesterone Metabolites in the Estrogen Primed Castrated Rat. Endocrine Soc, Washington, DC, Jun 1980. (C)

Hannan, C.J. and Lloyd, A.J.: Characteristics of the Interresponse Time of the Mongolian Gerbil. Psychonomic Soc, Phoenix, AZ, Nov 1979. (C)

Hannan, C.J., Lloyd, A.J., McCloskey, J.J.: The Rapid Avoidance Test of Gerbils After Unilateral Cerebral Ischemia. Soc Neurosci, Atlanta, GA, Nov 1979. (C)

Cowan, G.S.M., Bell, J., Harrell, H: Hematocrit Levels in 16,071 Basic Combat Trainees (BCTs) and Controls. AABB, Las Vegas, Nev, Nov 1979. (C)

Harris, R.W., Arensman, J.B., Moore, W.L. Jr.: Monomicrobial Bacterial Abscess Animal Model. Amer Soc Microbiol, Miami, FL, May 1980. (C)

Patterson, R.A. and Hannan, C.J.: Learned Helplessness in the Gerbil. Georgia Academy Sci, Macon, GA, Apr 1980. (C)

McPherson, J.C. III: Regulation of Gonadotropin Secretion in the Male Rat by Estradiol and Testosterone or Dihydrotestosterone Combinations. Georgia Academy Sci, Macon, GA, Apr 1980. (C)

DEPARTMENT OF MEDICINE

Moore, W.L. Jr.: Diagnosis and Management of Urinary Tract Infections: Diagnosis and Treatment of Bacterial Pneumonias. Atlanta Graduate Medical Assembly, Atlanta, GA, Mar 1980.

Moore, W.L. Jr.: Viral Infections - What's New in Diagnosis and Management: Venereal Disease - Update. Central State Hospital Staff, Milledgeville, GA, Mar 1980.

Moore, W.L. Jr.: Venereal Disease 1980 - Old Concepts, New Culprits: Intra-Abdominal and Pelvic Anaerobic Infections. Infectious Disease Symposium, Wilmington, DEL, May 1980.

Moore, W.L. Jr.: Childhood Diseases in the Young Adult. Medical College of Georgia, Augusta, GA, Dec 1979.

PRESENTATIONS

Reed, J.W.: Management of Thyroid Nodules. Medical Assn of Puerto Rico, Mayaguez, PR, Nov 1979.

Reed, J.W.: Hyperliperemia and Coronary Artery Disease. Medical Association of Puerto Rico, Mayaguez, PR, Nov 1979.

Reed, J.W.: Hypercalcemic Syndromes and Their Management. Medical Association of Puerto Rico, Mayaguez, PR, Nov 1979.

DEPARTMENT OF SURGERY

Powell, G.K.: Breast Cancer - A Second Opinion. Medical College of Georgia, Augusta, GA, Mar 80.

Powell, G.K.: The Mastectomy Patient. Amer Cancer Soc Reach to Recovery Group, Augusta, GA, Jul 1980

Barja, R.H.: Non-Union of Colle's Fractures. Soc Mil Orthopedic Surgeons, San Francisco, CA, Dec 1979.

Davies, R.S.: Operative Management of Hyperthyroidism. Gary P. Wratten Surgical Symposium, Walter Reed Army Medical Center, May 1980.

Piskun, W.S.: Neurosurgical Aspects of the Battered Child. Congress Neurological Surgeons, Las Vegas, NV, Oct 1979.

Piskun, W.S.: Neurology, Neurosurgery and the Air Crew Member. First Annual Symposium - Current Concepts in Army Aviation Medicine, Fort Rucker, AL, Apr 1980.

Jones, G.P.: Indications for Operation for Hyperthyroidism. Walter Reed Army Medical Center, May 1980.

Armitage, D.T.: Aspects in Motivation of Preventive Health Care. Medical College of Georgia Dental School, Apr 1980.

Chipman, M.: Headaches: Presentations, Course and Management. Medical Staff, Moncrief Army Hospital, Fort Jackson, SC, Sep 1980.

McCormack, J.C.: Group Therapy: A TA and Gestalt Model. Psychology Seminar, VA Med Center, Augusta, GA Nov 1979.

McCormack, J.C.: Adult Outpatient Psychotherapy. Augusta College Colloquium Series, Augusta, GA, Oct 1979.

Venezia, D.J. Jr.: The Rorschach Psychodiagnostic Test With an Emphasis on Exner's Comprehensive System. VA Medical Center, Augusta, GA, Feb 1980.

Treanor, J.J.: Sequelae of Closed Head Injury. Annual Aviation-Medicine Symposium, Fort Rucker, AL, Nov 1979.

PRESENTATIONS

DEPARTMENT OF OBSTETRICS AND GYNECOLOGY

Broadnax, G.B.: A Comparison of Prophylactic Antibiotic Regimens in Vaginal Hysterectomy. Armed Forces District, Amer College Obstetrics and Gynecologists, San Antonio, TX, Oct 1979.

DEPARTMENT OF PATHOLOGY

Quashnock, J.M.: Determination of AST Isoenzymes on the DuPont ACA. Soc Armed Forces Med Lab Scientists, San Antonio, TX, Oct 1979.

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Boe, G.P.: Current Events in the Clinical Laboratory Field. Illinois State Chapter, ISCLT, Elgin, IL, Oct 1979.

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PRESENTATIONS

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Shapiro, A.: Mental Status Examination: Purpose and Techniques. Medical College of Georgia, School of Nursing, Augusta, GA, Aug, Sep 1980.

Detail Summary Sheet

Date: 30 October 1980	Prot No.: 78-5	Status: Ongoing
Title: A Vascular Occlusion Stroke Model: I. A Technique for Evaluating Therapeutic Approach and Predisposing Factors.		
Start Date: February 1978	Est Comp Date: None	
Principal Investigator:	Facility:	
CST Charles L. Hannan, Jr., MSC, PhD	DDEANC	
Dept/Svc: Clinical Investigation, Neurology	Associate Investigators:	
Key Words:	COL Martin Chipman, MC	
Accumulative MEDCASE Cost: 0	Est Accumulative OMA Cost:\$10,000	Periodic Approved for continuation. Review Results
Study Objective: To evaluate predisposing factors and experimental therapies in the gerbil model of cerebral ischemic stroke.		

Technical Approach: See Progress.

Progress: NEW GERBIL STROKE MODEL. Variability in occurrence and extent of cerebral infarction with the unilateral carotid occlusion version of the gerbil stroke model is a serious limitation of the method. It was hypothesized that unilateral infarction could be more consistently obtained by limiting the reactive hyperemia through the countralateral carotid artery. It was observed in gerbils, which had both carotids exposed, that unilateral occlusion invariably resulted in distension of the patent carotid artery. Presumably, the animals with sufficient anterior communicating artery capacity would avoid infarction and those with limited interhemispheric blood flow capacity would develop infarction and probably die within 3 days. In an attempt to control for this variability a modified Ligaclip (Ethicon brand small tantalum ligating clip, LC-100) was used to restrict, but not prevent, blood flow in the patent right common carotid artery of gerbils that had their left common carotid artery completely occluded. To prevent complete closure of the ligating clip, an approximately 1 mm long segment of a 30 gauge needle was epoxied to the inner surface. Nineteen male retired breeder Mongolian gerbils (70-102 grams) were prepared as described above while under ketamine anesthesia (100 mg/kg, ip). The totally occluded left carotid artery was clamped with a standard small ligating clip and the artery cauterized distal to the occlusion. Mortality data was compiled for five days after

Protocol 78-5, Continued

which survivors were perfusion-fixed with buffered formalin. Horizontal sections of brain were histologically examined. All modified ligation clips were removed and measured under a microscope. Results are summarized below:

Day 5	n	Modified Clip Width (mm)		Gerbil Weight (gms)	
		Mean + SD	Range	Mean + SD	Range
Died	9	.20+.03	.15-.22	80.9+8.9	70-89
Survived	10	.24+.03	.20-.28	85.4+10.7	72-102

One-way analysis of variance reveals a significant difference ($p < .01$) between the clip widths of animals which died and those which survived. There was no significant difference in weight between these groups before the occlusion was induced. The mortality (47%) was higher in these animals than in other retired breeders given only a unilateral occlusion (unreported data) and points to the usefulness of this model; however, greater uniformity in the width of the flow-restricting clip must be attained.

GERBIL STROKE MODEL: GLUCOSE EFFECT. A version of the gerbil model for stroke where the left common carotid artery is occluded and a flow restricting hemostatic clip is applied to the right common carotid, was employed to evaluate the effect of glucose and xylazine. Four groups of male gerbils (59-86 grams) were prepared as explained above, under ketamine anesthesia and then treated as follows: 1) glucose group, 5 mg/kg (ip) glucose (50% w/v) immediately after occlusion; 2) xylazine group, 3 doses of xylazine (2 mg/kg, ip) at 1/2, 2 and 4 hours post occlusion; 3) glucose and xylazine group, both treatments as above; and 4) control group, no treatment. Mortality data was collected by days and gerbils surviving one week were perfusion fixed with 10% buffered formalin for histological evaluation.

Group(n)	Died	(%)	Infarcted	Normal
1. glucose(9)	8	(89)	0	1
2. xylazine(10)	5	(50)	2	3
3. glucose & xylazine(9)	8	(89)	0	1
4. control(21)	11	(52)	2	8

Mortality data indicated a significant difference between glucose and control groups $P(x^2) = .94$, and between glucose and xylazine groups, $P(x^2) = .99$ using the Chi square statistic. The severe toxic effect of glucose in this stroke model appeared to not be significantly affected by xylazine, which had no effect on mortality when given alone. Xylazine has been shown to reduce plasma insulin and somewhat increase plasma glucose. Xylazine was tolerated by the ischemic gerbil brain, while glucose administration, which should increase plasma glucose as well as insulin, was devastating. There were probably differences in the plasma glucose levels between groups which may explain the differences in mortality.

Detail Summary Sheet

Date: 30 October 1980		Prot No.: 78-6		Status: Terminated	
Title: A Vascular Occlusion Stroke Model: II. Permanent vs Temporary Vascular Occlusion.					
Start Date: February 1978			Est Comp Date:		
Principal Investigator:			Facility:		
CPT Charles J. Hannan, Jr., MSC			DDEAMC		
Dept/Svc: Clinical Investigation			Associate Investigators:		
Key Words:					
Accumulative MEDCASE		Est Accumulative		Periodic Not approved for continuation.	
Cost: 0		OMA Cost: \$100.00		Review Results	
Study Objective: To characterize differences between a permanent and temporary common carotid artery occlusion in the gerbil stroke model.					

Technical Approach: Groups were examined histopathologically and behaviorally (open field test) to determine characteristics associated with either permanent or temporary vascular occlusion.

Progress: No specific determinants could be found so this research approach will not be pursued.

Detail Summary Sheet

Date: 30 October 1980 Prot No.: 78-12 Status: Ongoing
 Title: Stroke Model: III. The Effect of Dexamethasone Therapy.

Start Date:		Est Comp Date:
Principal Investigator:		Facility:
CPT Charles J. Hamman, Jr., MSC		DDEAMC
Dept/Svc: Clinical Investigation		Associate Investigators:
Key Words:		
Accumulative MEDCASE	Est Accumulative	Periodic Not reviewed
Cost: 0	OMA Cost: 0	Review Results
Study Objective: To evaluate dexamethasone with DMSO vehicle as an experimental therapy in the gerbil stroke model.		

Technical Approach: See Protocol 78-5.

Progress: This project was delayed due to problems in the variability of the stroke model (see protocol 78-5). Completion is now possible and this project will soon be implemented.

Detail Summary Sheet

Date: 30 October 1980	Prot No.: 78-36	Status: Ongoing
Title: Stroke Model: IV. The Response of Brain Superoxide Dismutase to Ischemia.		

Start Date: January 1979	Est Comp Date:
Principal Investigator: CPT Charles J. Hannan, Jr., MSC	Facility: BDEAMC
Dept/Svc: Clinical Investigation	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost: 0	Est Accumulative OMA Cost:\$500.00
Periodic Approved for continuation. Review Results	
Study Objective: To measure activity of brain superoxide dismutase in gerbil brain made ischemic for various periods of time.	

Technical Approach: See Protocol 78-5.

Progress: Shortage of technical support has prevented more than minimal progress on this protocol which requires considerable talent and practice to perform.

Detail Summary Sheet

Date: 6 November 1980 Prot No.: 79-7 Status: Ongoing

Title: Control of Gonadotropin Secretion in the Male Rat.

Start Date: May 1979		Est Comp Date:
Principal Investigator:		Facility:
James C. McPherson, III, PhD, DAC		DDEAMC
Dept/Svc: Clinical Investigation		Associate Investigators:
Key Words:		
Gonadotropins		
Male		
Accumulative MEDCASE	Est Accumulative	Periodic Approved for continuation.
Cost: \$6,000.00	OMA Cost: \$300.00	Review Results

Study Objective: Regulation of gonadotropin secretion has wide applications in the control or regulation of both fertility and infertility. A better understanding of the relationships among the target organ (ovary or testis), the pituitary, the hypothalamus and higher brain centers has allowed new advances for the regulation of fertility in the female with reduced levels of steroids and fewer side effects. At the same time these studies have added new insights, enabling the reversal of infertility in some of the female population. The complexity of the regulation of gonadotropin secretion in the male and a lack of understanding of the differences (Con'td)

Technical Approach: Twenty-six day old male rats were castrated under halothane anesthesia. Replacement steroid treatment was begun at the time of surgery and continued for five days. Daily dosages were divided into two injections to more closely stimulate physiological conditions. At the completion of the treatment period, the animals were sacrificed under halothane anesthesia by cardiac puncture. Seminal vesicles and ventral prostate were removed, cleaned of fat, blotted dry and weighed. The collected blood was analyzed by RIA for serum FSH and LH using NIAMD kits in our own laboratory. Appropriate intact and castrate controls were used. Statistics were performed using Duncan's Multi-Range test. Replacement steroid treatments involve either single or combinations of estrogens, progestins and/or androgens.

Progress: Progress on this protocol has been hampered by a lack of basic laboratory equipment including, but not limited to, a radioisotope hood (now acquired and installed), a gamma counter (now using one from the Department of Pathology), a freeze dryer (now acquired but not installed), a lack of personnel and a lack of adequate laboratory animal support. The acquisition of a liquid scintillation counter would add new dimensions to this study. With the initial findings of this protocol, a new understanding of the regulation and control of gonadotropin secretion in the male is emerging. A better understanding of the differences between the male and the female is at hand. This and future studies will make a significant contribution to fertility and infertility in both the male and female.

Protocol 79-7 Continued

Study Objective: in regulation of gonadotropin secretion between the male and female have compounded the problem. These studies have added significant contributions to the regulation of gonadotropin secretion in the male by the use of an immature rat model in which gonadotropin secretion is very sensitive to steroids. These studies, for the first time, have demonstrated a gonadotropin surge in the male, very similar to that seen in the female before ovulation, which is induced by "female" hormones, estrogen and progesterone and not induced by "male" hormones, androgens. These studies suggest that the male has a cyclic center for gonadotropin release similar to that seen in the female as well as a tonic center gonadotropin recognized in both sexes and suggests that some change occurs during early neo-natal life in the male which renders this cyclic center unoperative under normal male control. This change appears to be a change in threshold sensitivity of the hypothalamus and/or higher brain centers to estrogen.

Detail Summary Sheet

Date: 6 November 1980 Prot No.: 79-19 Status: Ongoing
 Title: Gastrointestinal Hormones in Non-Ionic Surface Active Agent Induced Delay of Gastric Emptying.

Start Date: January 1980		Est Comp Date:
Principal Investigator: James C. McPherson, III, PhD, DAC		Facility: DDEAMC
Dept/Svc: Clinical Investigation		Associate Investigators: James C. McPherson, Jr., MD Medical College of Georgia
Key Words: Gastric Emptying		
Accumulative MEDCASE Cost: None	Est Accumulative OMA Cost: \$700.00	Periodic Approved for continuation. Review Results

Study Objective: The treatment of fat embolism syndrome with non-ionic surface active agents following trauma have produced a number of unique findings. Earlier, while evaluating the protective nature of some of these non-ionic surface active agents in the treatment of experimentally induced fat embolism syndrome (Federation Proc, 39:305, 1980), we noticed a delayed gastric emptying time. These studies were designed to evaluate this delayed gastric emptying time from a gastrointestinal hormone point of view. Were the release of cholecystokinin and/or secretin in relation to gastric emptying altered? A number of companies have been interested in (Cont'd)

Technical Approach: Male rats, weighing 330-350 gm, will be fasted for 48 hours with water ad libidum and fed 10 ml of 20% sucrose via stomach tube after 8 and 24 hours of fasting. Preliminary studies demonstrate this technique lowers the fasting stomach contents. Groups of 10 animals each will receive intravenous doses of saline (controls), pluronic F-68 (800 mg/kg) and Triton WR-1339 (100,400, and 800 mg/kg). Thirty minutes later the animals will be tube fed a commercially available tube feeding diet. Groups of 10 animals of each dose level will be sacrificed after another 1,2,4 or 8 hours. Blood samples will be obtained by cardiac puncture before the injection of saline or the surface active agent and at the termination of the experiment for the analysis of cholecystokinin and secretin. Gastric emptying will be determined by ligation of the stomach and weighing the dried stomach contents as compared to the dried contents of the fed diet.

Progress: In order to quantitate the hormones involved in gastric emptying, RIA's are being developed in our laboratories. Three rabbits were injected at multiple sites with secretin, obtained from ICN Pharmaceuticals, dissolved in Freund's Complete Adjuvant. Three additional rabbits were injected at multiple sites with Cholecystokinin, obtained from Sigma Chemical Co., dissolved in Freund's Complete Adjuvant. Following this initial inoculation for antibody production, one rabbit injected with secretin died. After a reasonable length of time following the initial booster, the rabbits were boosted with the appropriate antigen then boosted again before being bled for antibody titer and specificity studies three days later. At the present time, these serum samples are undergoing evaluation for antibody titers and antigen specificity.

Protocol 79-19 Continued

Study Objective: this finding from another point of view, do these agents affect an area of the brain which may affect hunger. If so these agents may be helpful in a weight control program.

Detail Summary Sheet

Date: 6 November 1980		Prot No.: 79-20	Status: Ongoing
Title: Examination of Multi-Microbial Abscesses in Animal Models: I. Development of Abscess Implantation Methodology.			
Start Date: April 1979		Est Comp Date: May 1981	
Principal Investigator:		Facility:	
CPT Richard W. Harris, MSC		DDEAMC	
Dept/Svc: Clinical Investigation, Medicine		Associate Investigators:	
Key Words:		MAJ J. Bruce Arensman, VC COL William L. Moore, Jr., MC	
Accumulative MEDCASE Cost: -	Est Accumulative OMA Cost: -	Periodic Approved for continuation. Review Results	
Study Objective: To determine the most effective methods for examination of bacterial abscesses in an animal model involving continuous sampling.			

Technical Approach: Gelatin capsules with Bacteroides fragilis and either sterile fecal material or soft agar were implanted in rabbits.

Progress: Palpable abscesses were produced and able to be sampled. The fecal implants produced abscesses in three to seven days. Soft agar implants required three weeks to produce palpable abscesses.

Detail Summary Sheet

Date: 10 November 1980		Prot No.: 79-21	Status: Ongoing
Title: The Experimental Fat Embolism Syndrome: An Electron Microscopic Study of Lung in Three Models.			
Start Date: June 1980		Est Comp Date: August 1981	
Principal Investigator:		Facility:	
Mr. Jack A. Horner, DAC		DDEAMC	
Dept/Svc: Clinical Investigation		Associate Investigators:	
Key Words:		James C. McPherson, III, PhD	
Fat Embolism		James C. McPherson, Jr., M.D.	
Electron Microscopy			
Accumulative MEDCASE Cost: -	Est Accumulative OMA Cost: \$100.00	Periodic Approved for continuation. Review Results	

Study Objective: Experimental fat embolism syndrome is usually induced by one of five techniques: 1) fracture of the femur of an animal, 2) injection of extracted or homogenized adipose tissue from a same species donor, 3) injections of olive oil or purified triolein, 4) injection of oleic acid, or 5) injection of mineral oil (all injections given intravenously). In this study the similarity and differences, if any, in these last three techniques (olive oil, oleic acid, and mineral oil) will be investigated.

Technical Approach: Fat embolism is a major (although frequently undiagnosed unless severe) complication in patients with fractures of the long bones and/or severe trauma. The etiological mechanism of this syndrome is still unsettled. The two mechanisms most widely accepted are (I) fat from the bone marrow of fractured bones or traumatized adipose tissue enter into small broken veins and travel to the lung where blockage of the capillaries and arterioles occur and (II) after trauma, the circulating lipoproteins in blood coalesce to form globules of fat large enough to block the capillaries of the lung. In addition, once the fat has blocked a capillary or arteriole, the apthogenic events which follow are unclear. The major effect may be a simple blockage but some investigators believe the most harmful effects result from the release of free fatty acids from the "trapped" fat globules in the lung. This study will attempt to establish the differences which could be important in the clinical syndrome by examining a mineral oil model (pure blockage with no possible release of free (Cont'd)

Progress: The initial start of this study was delayed while awaiting the availability of animal support facilities. A unique and crucial aspect of this study was the intended use of a fluorocarbon, FC-80(3M Company), as the vehicle for osmium tetroxide for primary intratracheal fixation of the lung. This method takes advantage of the extremely low surface tension of FC-80 and results in excellent ultrastructural preservation of pulmonary tissues. Unfortunately the FC-80 fluorocarbon is no longer being manufactured due to the limited market for its use. We are currently evaluating several alternative methods for pulmonary perfusion including the possible use of the fluorocarbon carrier component of Fluosol-43 (Green Cross Corp., Osaka, Japan), the perfluorochemical artificial blood recently introduced for experimental investigations. Pending the outcome of the Fluosol-43 evaluation, it appears that the most acceptable alternative method to fluorocarbon/fixative administration is the inhalation of osmium tetroxide vapors followed by low pressure perfusion of phosphate buffered osmium and cacodylate buffered glutaraldehyde. Further evaluation of these techniques is required prior to full implementation of this study.

Protocol 79-21 Continued

Technical Approach: fatty acid from the globules), oleic acid (effect of free fatty acid only), and olive oil (fat capable of hydrolysis to yield free fatty acids). This study may add to our basic understanding of the events in the pathogenesis of the clinical fat embolism syndrome and suggest the basis of new methods of treatment.

Detail Summary Sheet

Date: 6 November 1980		Prot No.: 79-22	Status: Ongoing
Title: The Bolus Technique for Production of Experimental Fat Embolism Syndrome Compared with a More Physiological Technique.			
Start Date: July 1980		Est Comm Date:	
Principal Investigator:		Facility:	
James C. McPherson, III, PhD, DAC		DDEAMC	
Dept/Svc: Clinical Investigation		Associate Investigators:	
Key Words:		MAJ J. Bruce Arensman, VC	
Fat Embolism Syndrome			
Accumulative MEDCASE Cost: -	Est Accumulative OMA Cost: \$600.00	Periodic Approved for continuation. Review Results	

Study Objective: The clinical syndrome known as fat embolism is a too frequent fatal complication of trauma. Little new information has been forthcoming on the basic understanding of the pathoanatomic or pathophysiologic mechanisms in the syndrome. No new experimental models have evolved. The experimental fat embolism syndrome is usually produced by the intravenous injection of a bolus of olive, oil, homologous fat on oleic acid over a short time interval (afew seconds to 1-3 minutes). With these types of studies, the LD50 of olive oil has been determined in dogs, rabbits and rats. This method of administration does not correspond to the entry (Cont'd)

Technical Approach: Male rats, weighing 300-320 gms, will have a catheter positioned in the jugular vein while under halothane anesthesia. Normal saline will be infused at a slow rate until the animals have recovered completely from anesthesia. At this time alumina treated olive oil will be infused via the cannula at a slow constant constant rate with an infusion pump. Various doses will be infused until an LD50 can be calculated. Ten animals will be used per group. Animals will be observed for four days after infusion. Similar animals will be injected using the bolus technique and an LD50 calculated. All animals that die will be necropsied for confirmation of the diagnosis of fat embolism by determining visual hemorrhage in the lungs, edema (wet weight) and microscopic demonstration of fat globules in samples of the lung. All animals which survive will be euthanized on the fifth post injection day and the same three studies made on the lungs. The LD50 of the two groups will be compared statistically.

Progress: Progress on this research project was initially hampered by the lack of an adequate infusion pump. The study is now under way; however, problems exist in obtaining and housing animals which do not suffer from chronic lung infection. Preliminary results indicate a difference in the LD50 between the two groups.

Protocol 79-22 Continued

Study Objective: of fat into the circulation in the clinical syndrome as believed by most investigators since the fat from the bone marrow of a fractured long bone probably enters via torn small veins over a long period of time (probably several hours). To test the usual model, we propose to compare the LD50 of animals injected rapidly with the LD50 of animals injected over a longer time period (4 hrs). This study should support the continued use of the bolus technique for the production of the experimental fat embolism syndrome or suggest an alternative technique which theoretically more nearly approaches the events believed to occur in the clinical syndrome.

Detail Summary Sheet

Date: 6 November 1980 Prot No.: 79-23 Status: Ongoing
 Title: Examination of Multi-Microbial Abscesses in Animal Models: II. Morphological and Bacteriological Comparison

Start Date: April 1979	Est Comp Date: May 1981
Principal Investigator: CPT Richard W. Harris, MSC	Facility: DDEAMC
Dept/Svc: Clinical Investigation	Associate Investigators: Mr. Jack A. Horner, DAC
Key Words:	
Accumulative MEDCASE Cost: -	Est Accumulative OMA Cost: -
	Periodic Approved for continuation. Review Results

Study Objective: To examine bacteriological and physiological parameters of an animal abscess model involving continuous sampling.

Technical Approach: Rabbits were implanted subcutaneously with gelatin capsules containing sterile human feces (control) or feces with Bacteroides fragilis (B.F.). Groups of 5 control and 5 B.F. inocula were sacrificed at 3 and 7 days postimplantation and examined for abscess size and formation, hematology counts, SMAC counts, abscess bacterial colony counts and histopathology of selected organs.

Progress: Both control and B.F. implanted rabbits produced abscess by day 3 which were edematous and loosely defined, but were more clearly encapsulated by day 7. Bacteriological plate counts were 1.10^9 organisms/ml abscess fluid at both 3 and 7 days in pure culture. Hematological examination indicated a slight increase in WBC counts and a decrease in hematocrit. SMAC were elevated for CPK and decreased for alkaline phosphatase. Histopathology of other organs was unremarkable.

Detail Summary Sheet

Date: 10 November 1980 Prot No.: 79-31 Status: Ongoing
 Title: Hematologic & Biochemical Effects of Xylazine on Dogs.

Start Date:		Est Comp Date:
Principal Investigator:		Facility:
MAJ J. Bruce Arensman, VC		DDEAMC
Dept/Svc: Clinical Investigation		Associate Investigators:
Key Words:		James C. McPherson, III, PhD
Accumulative MEDCASE Cost: -	Est Accumulative OMA Cost: -	Periodic Approved for continuation. Review Results

Study Objective: To evaluate the effects of the tranquilizer, xylazine, on hematologic, biochemical, and insulin levels in dogs and compare to known response ruminants.

Technical Approach: After collection of blood samples at timed intervals, before and after the administration of xylazine, CBC's, SMAC-16, and insulin assays will be performed.

Progress: Due to lack of adequate gamma counting equipment and NRC License problems (now corrected), this protocol has been stagnated. Alternative approaches have been investigated and gamma counting using Pathology Department equipment is feasible.

Detail Summary Sheet

Date: 6 November 1980	Prot No.: 79-32	Status: Completed
Title: Effect of Length of Administration and Dose of Testosterone on Serum Gonadotropins in the Male Rat.		
Start Date: July 1979	Est Comp Date: April 1980	
Principal Investigator: James C. McPherson, III, PhD, DAC	Facility: DDEAMC	
Dept/Svc: Clinical Investigation	Associate Investigators:	
Key Words: Gonadotropin Secretion Steroids Male		
Accumulative MEDCASE Cost: -	Est Accumulative OMA Cost: \$900.00	Periodic Not approved for continuation. Review Results

Study Objective: In reviewing the literature, the methodology used in assessing the effect of gonadal steroids in both the male and female rat have been widely varied. More recent investigations by this investigator and other investigators have utilized a more uniform methodology using the female rat. However, widely varying methodologies have remained using the male, mainly because of the long-held belief that androgen action in the male required an extended period of administration for the full extent of its actions to be observed. The present investigation was undertaken to evaluate the length of androgen administration on serum gonadotropins and (Cont'd)

Technical Approach: Immature male rats, castrated at 26 days of age, were treated for five or seven days post-operatively with testosterone. Daily dosages were begun at the time of surgery and were divided into two subcutaneous injections, one morning and one early evening, in order to more closely simulate physiological conditions. Dosages for the two sets of experiments were calculated on the basis of 70 gm and 100 gm body weights. At the completion of the treatment period, animals were sacrificed under halothane anesthesia, blood withdrawn by cardiac puncture and secondary sex organs removed, cleaned of fat, blotted and weighed. Serum gonadotropins were run in our laboratory by RIA using NIAMD kits for RFSH and RLH. Each experimental group contained at least six animals. The results were compared statistically using Duncan's Multi-Range Test.

Progress: The results confirm previous results that increasing concentrations of testosterone from 100 to 800 $\mu\text{g/kg/day}$ suppress serum FSH and LH from castrate levels in a dose-dependent manner. These results extend those found previously by documenting that there is no significant difference in either response of serum gonadotropins nor secondary sex organ weights between groups treated for five or seven days with the same dose of testosterone. Furthermore, the changes associated with doses based on 70 gm or 100 gm body weights were not significantly different. From these data, the physiological dose range (PDR) could be calculated. The PDR is defined as that dose of steroid necessary to restore the weight of an organ of a castrate animal to the weight of an intact control. For testosterone, the PDR for seminal vesicle is 100 $\mu\text{g/kg/day}$ and for the ventral prostate is 400 $\mu\text{g/kg/day}$. Within the PDR for the seminal vesicle, both FSH and LH were suppressed to intact control levels, while within the PDR for the ventral prostate FSH was not suppressed from castrate control levels. However, LH was significantly suppressed below castrate control levels but was still significantly elevated above intact control levels. These results indicate that androgen actions in the male are similar to estrogen actions in the female with respect to control of gonadotropin secretion and the time period necessary for those changes to take place.

Protocol 79-32 Continued

Study Objective: secondary sexual organs, and to evaluate the dose of androgen administration on these same parameters. The dose was of interest since these animals are utilized in experiments when they are rapidly gaining weight.

Detail Summary Sheet

Date: 30 October 1980 Prot No.: 79-36 Status: Ongoing
 Title: Chronic Medications and HDL-Cholesterol Screen.

Start Date: August 1980	Est Comp Date:
Principal Investigator:	Facility:
CPT Charles J. Hannan, Jr., MSC, PhD	DDEAMC
Dept/Svc: Clinical Investigation, Family Practice, Medicine, Neurology	Associate Investigators:
Key Words:	CPT Paul E. Martin, MC COL William L. Moore, Jr., MC LTC Edward Mendoza, MC
Accumulative MEDCASE	Est Accumulative
Cost: 0	OMA Cost: 0
Periodic Not reviewed. Review Results	
Study Objective: To monitor the effect of chronic medications on plasma high density lipoprotein cholesterol (HDL-Chol.).	

Technical Approach: Plasma level of HDL-Chol. is determined in volunteers before beginning a chronic (greater than 3 week) program of a drug followed by a post drug HDL-Chol. level.

Progress: The first patients were entered on this protocol in August, 1980. Data is starting to be accumulated, but no conclusions can be made yet.

Detail Summary Sheet

Date: 6 November 1980 Prot No.: 80-13 Status: Ongoing
 Title: Natural Occurring Immunoglobulins in Human Serum to Bacteroides fragilis.

Start Date: March 1980	Est Comp Date: February 1981
Principal Investigator: CPT Richard W. Harris, MSC	Facility: DDEAMC and VA Medical Center
Dept/Svc: Clinical Investigation	Associate Investigators: T.B. Buxton, VA J.P. Rissing, VA
Key Words:	
Accumulative MEDCASE Cost: -	Est Accumulative OMA Cost: -
Periodic Approved for continuation. Review Results	

Study Objective: To determine the IgM and IgG serum levels in a population of normal healthy human subjects using enzyme linked immunosorbent assay.

Technical Approach: Serum from 200 blood donors will be collected and a double antibody sandwich immunoassay technique using lipopolysacchride of Bacteroides fragilis as the solid phase will be performed using antisera to human IgG and IgM.

Progress: Serums are now being collected.

Detail Summary Sheet

Date: 10 November 1980 Prot No.: 80-18 Status: Ongoing
 Title: Conduit from Thoracic Duct to Esophagus: Application of New Surgical Procedure.

Start Date: March 1980		Est Comp Date:
Principal Investigator:		Facility:
MAJ J. Bruce Arensman, VC		DDEAMC
Dept/Svc: Clinical Investigation		Associate Investigators:
Key Words:		A.L. Humphries, MC
		Medical College of Georgia
Accumulative MEDCASE	Est Accumulative	Periodic Approved for continuation.
Cost: -	OMA Cost: -	Review Results

Study Objective: To prove the efficacy of the proposed surgical procedure and to make a practical application of it. The flow of lymph into the gastrointestinal tract will result in destruction of lymphocytes and reduction of serum IgG and IgA levels to create a form of immunosuppression.

Technical Approach: Using the left jugular vein and right carotid artery, an A-V fistula is formed with the carotid artery routed through the esophageal musculature in proximity to the submucosa. In a second operation two weeks later, the carotid and brachiocephalic vein are ligated and the lumen of the carotid opened into the esophageal lumen. Lymph can then flow from the thoracic duct through the jugular, through the transplanted carotid, into the esophagus.

Progress: Six animals have had surgery. The first portion of the procedure is now successful; however, the second portion has yet to have a successful outcome. Further study and work is needed.

Detail Summary Sheet

Date: 30 October 1980 Prot No.: 80-21 Status: Ongoing
 Title: Cognitive Style in Acute Schizophrenics

Start Date: July 1980	Est Comp Date: 1 September 1981
Principal Investigator: CPT Charles J. Hannan, MSC, PhD	Facility: DDEAMC
Dept/Svc: Clinical Investigation, Psychiatry	Associate Investigators: LTC Matthew E. Levine, MC Dr. Raymond Klein, PhD
Key Words:	
Accumulative MEDCASE Cost: 0	Est Accumulative OMA Cost: \$200.00
	Periodic Approved for continuation. Review Results

Study Objective: To determine if normal rhythms of cognitive style (verbal versus spatial performance) are present in schizophrenic volunteers.

Technical Approach: Volunteers with a diagnosis of schizophrenia take the cognitive style test intermittently for an entire day to reveal patterns of verbal and spatial ability during an extended period.

Progress: Three volunteer patients have been evaluated with the cognitive style test as of this date, and none has been subjected to computer analysis, so conclusions are not available yet.

Detail Summary Sheet

Date: 17 November 1980 Prot No.: 30-29 Status: Ongoing
 Title: Differentiation of Bacteria in vivo by Gas Liquid Chromatography.

Start Date:		Est Comp Date:
Principal Investigator: CPT Richard W. Harris, MSC		Facility: DDEAMC
Dept/Svc: Clinical Investigation		Associate Investigators: MAJ J. Bruce Arensman, VC COL William L. Moore, Jr., MC
Key Words:		
Accumulative MEDCASE Cost: -	Est Accumulative OMA Cost: -	Periodic Review Results <u>Not Reviewed.</u>

Study Objective: To determine patterns of metabolite production by electron capture gas chromatography in an abscess animal model.

Technical Approach: Exudate from the rabbit model will be used to compare monomicrobial abscesses. Organisms will be implanted with soft agar and exudate will be examined upon abscess formation. Serum will be drawn for determination of metabolites.

Progress: Local approval in September 1980, insufficient time for implementation this fiscal year.

Detail Summary Sheet

Date: 17 November 1980 Prot No.: 80-30 Status: Ongoing
 Title: Detection of B. Fragilis Antigen in vivo.

Start Date:		Est Comp Date:
Principal Investigator: CPT Richard W. Harris, MSC		Facility: DDEANIC
Dept/Svc: Clinical Investigation		Associate Investigators: COL William L. Moore, Jr., MC J. Peter Rissing, MD, VA Thomas B. Buxton, M.S. (ASCP)
Key Words:		
Accumulative MEDCASE Cost: -	Est Accumulative OMA Cost: -	Periodic Review Results Not reviewed.

Study Objective: To use the enzyme linked immunoassay (ELISA) to detect B. fragilis in serum in an animal model.

Technical Approach: Two separate determinations will be made; a) Detection of antigen in a rat bacteremia model, and b) detection of antigen in a rabbit abscess model.

Progress: Local approval in September 1980, insufficient time for implementation this fiscal year.

Detail Summary Sheet

Date: 14 October 1980		Prot No.: 78-38		Status: Ongoing	
Title: Efficacy of Immunotherapy for Systemic Allergic Reaction to Imported Fire Ant Stings, Part I.					
Start Date: August 1979			Est Comp Date:		
Principal Investigator:			Facility:		
COL Chester T. Stafford, MC			DDEAMC		
Dept/Svc: Medicine/Allergy-Immunology, Clinical Investigation			Associate Investigators:		
Key Words:			Dr. Robert B. Rhoades, MD Medical College of Georgia CPT Charles J. Hannan, Jr., PhD, MS		
Accumulative MEDCASE Cost: None		Est Accumulative OMA Cost: \$400.00		Periodic Approved for continuation. Review Results	

Study Objective: (1) To compare the skin test reactivity of fire ant venom and its components with whole body extracts (WBE) of fire ants in patients allergic to stings of the imported fire ant. (2) To compare skin test reactivity with in vitro immunologic studies (RAST and Histamine release). (3) To determine the pretreatment immunologic status of fire ant sensitive patients prior to their participation in studies comparing the relative efficacy of immunotherapy with fire ant venom (Part III Protocol) versus whole body extracts (Part II Protocol) versus placebo; pending DA approval.

Technical Approach: In order to meet FDA requirements for beginning human skin testing, the fire ant products must be evaluated for toxicity and uniformity of composition according to Title 10, US Code.

Progress: Toxicity testing in the mouse is complete (whole body extract of fire ant found non-toxic). Enzyme composition of the extract has been started and will continue with the primary effort being to assay for phospholipase. Technical personnel to support these laboratory procedures has hindered progress; however, a temporary hire technician is expected shortly.

Detail Summary Sheet

Date: 14 October 1980 Prot No.: 79-34 Status: Ongoing
 Title: Growth of Human Tumor Stem Cell Colonies in Soft Agar.

Start Date: January 1980		Est. Date:
Principal Investigator:		Agency:
MAJ James E. Boyd, MC		DDEAMC
Dept/Svc: Medicine/Oncology/Hematology		Associate Investigators:
Key Words:		CPT Cherry Gaffney, MC
		CPT Ion Stewart, MS
Accumulative MEDCASE	Est Accumulative	Periodic Approved for continuation.
Cost: -	OMA Cost: -	Review Results

Study Objective: To grow human tumor stem cell colonies in soft agar for the purpose of studying growth kinetics, sensitivity to chemotherapeutic and hormonal agents, and to study estrogen receptors in the cytoplasm of malignant cells by immunofluorescent assay.

Technical Approach: Single cell suspension of the human cancer cells will be obtained from pleural, paracardial or ascitic fluid. These cells will be suspended in a 0.3 percent agar overlayer with a 0.5 percent agar underlayer providing necessary nutrients for growth. Various hormones and/or chemotherapeutic agents can be mixed with the tumor cells in the overlayer to determine toxicity to the cells by measurement of the number of colonies which grow subsequently. Additionally, a fluorescent labeled conjugate is being studied which will tag estrogen receptors. This is particularly of value in determining responsiveness of breast cancer to hormone therapy. The immunofluorescent assay is being developed to assay the percentage of colonies which are estrogen receptor positive.

Progress: During the past year, slow progress has been made. All necessary agents have arrived and appropriate solutions have been made. With the assistance of the Department of Pathology, research is ongoing in the development of the fluorescein conjugate for the immunofluorescent assay of estrogen receptors.

Detail Summary Sheet

Date: 14 October 1980 Prot No.: 79-35 Status: Ongoing
 Title: Rapid Diagnosis of Viral Respiratory Infection.

Start Date: February 1980		Est Comp Date: June 1981
Principal Investigator: LTC David R. Haburchak, MC		Facility: DDEAMC
Dept./Svc: Medicine/Infectious Disease, Clinical Investigation		Associate Investigators: CPT Richard W. Harris, MS
Key Words:		
Accumulative MEDCASE Cost: None	Est Accumulative OMA Cost: None	Periodic Approved for continuation. Review Results

Study Objective: To determine feasibility of rapid viral diagnosis in patients with ARD by methods of direct electron microscopy and enzyme-linked immuno-
 absorbant assay.

Technical Approach: Throat swabs from patients with ARD are inoculated into holding medium, split, cultured, processed for EM and ELISA.

Progress: Technique for EM has improved to capability of recognizing virus from positive control stocks. Major emphasis now is on methods of concentrating virus after specimen collection.

ELISA-reagents are being procured and initial control antigens studied.

Detail Summary Sheet

Date: 12 November 1980 Prot No.: 80-2 Status: Terminated
 Title: Evaluation of Cimetidine Administration Before Abdominal Technetium Scans to Improve the Detection of Ectopic Gastric Mucosa.

Start Date: March 1980	Est Comp Date: June 1980
Principal Investigator: CPT Jaime Rivera, MC	Facility: DDEAMC
Dept/Svc: Medicine	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost: -	Est Accumulative OMA Cost: -
	Periodic Review Results Not reviewed.

Study Objective: To evaluate the sensitivity and specificity of technetium scanning for Meckel's Diverticula with and without Cimetidine pre-treatment.

Technical Approach: Approximately 15 dogs will be divided into three groups: a) Control, b) Animals in which gastric mucosa is transplanted to the terminal ileum, and c) Gastric mucosa implanted of different sizes. Method: a) Scintigraphic images after 10 mci of Per technetate IV, b) preparation - fasting overnight, c) abdominal flow study in the anterior position and frames obtained at two second intervals for a total of 30 frames, d) static images obtained immediately following the flow study. First image of 500K (then for the same time) the first 5 minutes, then another image at 30 minutes, and at 60 minutes.

Progress: Amount of radioactive material on NRC License was not sufficient to allow this study to be performed on dogs. Amendment to license has been submitted to NRC to correct this situation.

Detail Summary Sheet

Date: 14 October 1980 Prot No.: 80-14(WRAMC 7915) Status: Ongoing
 Title: Prevention of Gonadal Damage in Women Treated with Combination Chemotherapy or Radiotherapy Below the Diaphragm for Hodgkin's or Non-Hodgkin's Lymphoma.

Start Date:	Est Comp Date:
Principal Investigator: MAJ James F. Boyd, MC	Facility: DDEAMC
Dept/Svc: Medicine/Oncology-Hematology	Associate Investigators: MAJ Russell Burgess, MC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Approved for continuation. Review Results
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Study Objective: To determine whether suppression of gonadal function by oral contraceptives in females and by testosterone in males will protect these individuals from subsequent damage to the gonads and sterility as a result of radiation therapy or chemotherapy for the treatment of Hodgkin's disease or non-Hodgkin's lymphoma.

Technical Approach: Pre-treatment the patients will undergo an endocrine evaluation including baseline LH, FSH, prolactin and estradiol along with menstrual history in females, and in males the baseline studies will include LH, FSH, testosterone and semen analysis. If possible, ovarian biopsy and testicular biopsy will be obtained pre-treatment. The women will be placed on oral contraceptives and the men will be placed on IM-testosterone given on a weekly basis for at least two weeks prior to therapy. The patients will remain on these agents throughout their therapy and at the completion of chemotherapy and/or radiation therapy, their endocrine evaluation will be repeated. Biopsies will not be repeated.

Progress: Due to the lack of eligible patients for this protocol, no individual has been placed on the protocol from DDEAMC.

Detail Summary Sheet

Date: 28 October 1980		Prot No.: 80-15(WRAMC7910) Status: Ongoing	
Title: Prevention of Gonadal Damage in Men Treated with Combination Chemotherapy/ Radiotherapy for Hodgkin's Disease and Non-Hodgkin's Lymphomas. Addendum #1 to WRAMC Protocol 7810.			
Start Date: July 1980		Est Comp Date:	
Principal Investigator:		Facility:	
MAJ James Boyd, MC		DDEAMC	
Dept/Svc: Medicine/Oncology-Hematology		Associate Investigators:	
Key Words:		MAJ Russell Burgess, MC	
Accumulative MEDCASE	Est Accumulative	Periodic Approved for continuation.	
Cost: 0	OMA Cost: 0	Review Results	

Study Objective: To prevent permanent infertility and alterations in normal sexual function caused by combination chemotherapy in the treatment of Hodgkin's disease or histiocytic lymphoma. This is to extend WRAMC Protocol 7810 which was limited to Hodgkin's disease and histiocytic lymphoma.

Technical Approach: To study all men ages 18-45 with Hodgkin's disease or non-Hodgkin's lymphoma prior to chemotherapy or infradiaphragmatic irradiation. Patients who have previously received chemotherapy or infradiaphragmatic irradiation will be excluded from this study, as will patients with known history of infertility, chromosomal abnormalities, or prostatic hypertrophy.

Progress: Due to lack of eligible patients for this protocol, no individual has been placed on the protocol from DDEAMC.

Detail Summary Sheet

Date: 17 November 1980 Prot No.: 80-28 Status: Ongoing
 Title: Antimicrobial Therapy in an Animal Abscess Model.

Start Date:	Est Comp Date:
Principal Investigator: COL William L. Moore, Jr., MC	Facility: DDEAMC
Dept/Svc: Medicine, Clinical Investigation	Associate Investigators: MAJ J. Bruce Arensman, VC CPT Richard W. Harris, MSC
Key Words:	
Accumulative MEDCASE Cost: -	Est Accumulative OMA Cost: -
	Periodic Review Results Not reviewed

Study Objective: To develop an appropriate methodology for examination of effects of antibiotics on monomicrobial and polymicrobial abscesses.

Technical Approach: In order to produce an encapsulated virulent strain, all stock organisms studied will be passed through a mouse or rat by s.c. injection with soft agar. The aspirated organism will then be used for rabbit inoculation.

Progress: Local approval in September 1980, insufficient time for implementation this fiscal year.

Detail Summary Sheet

Date: 18 November 1980		Prot No.: 80-34		Status: Ongoing	
Title: Correlation of Glycosylated Hemoglobin with Different Degrees of Glucose Intolerance and Possible Standardization of These Values for the Use in the Detection of Diabetes.					
Start Date:			Est Comp Date:		
Principal Investigator:			Facility:		
CPT Gildred E. Rivera-Colon, MC			DDEAMC		
Dept/Svc: Medicine, Pathology			Associate Investigators:		
Key Words:			COL Ronny J. Sayers, MC		
Accumulative MEDCASE Cost: -		Est Accumulative OMA Cost: -		Periodic Review Results Not reviewed.	

Study Objective: To investigate if the determination of glycosylated hemoglobin (GHb) can substitute the Oral Glucose Tolerance Test (O.G.T.T.) in the detection of diabetes and to see if it can be further standardized to be able to differentiate overt diabetes from those with impaired glucose tolerance.

Technical Approach:

Progress: Local approval in September 1980, insufficient time for implementation in this fiscal year.

Detail Summary Sheet

Date: 14 October 1980	Test No.: 80-9	Status: Completed
Title: Double-Staining Procedure for Fluorescent Treponemal Antibody Absorption (FTA-ABS) Test.		
Start Date: February 1980	Est Comm Date: ---	
Principal Investigator:	Facility:	
LTC Charles L. Latke, MS	DDEAMC	
Dept/Svc: Pathology	Associate Investigators:	
	Janet H. Riggsbee, DAC	
Key Words:		
Syphilis serodiagnosis, Fluorescent treponemal Antibody		
Accumulative MEDCASE	Est Accumulative	Periodic Not approved for continuation. Review Results
Cost: None	OMA Cost: None	
Study Objective: To evaluate the double-staining fluorescent antibody-absorption (FTA-ABS) test for practical laboratory use.		

Technical Approach: A comparison of conventional FTA-ABS and the double-staining FTA-ABS was performed on fresh and stored frozen samples of known syphilitics and normals.

Progress: The results of double-staining FTA-ABS demonstrated a high correlation to the conventional method. The elimination of the dark field condensor and the use of high magnification in the double-staining procedure was a technical improvement over the FTA-ABS method.

Detail Summary Sheet

Date: 14 October 1980		Prot No.: 80-16		Status: Completed	
Title: Evaluation Study on Sulfamethoxazole-Trimethoprim Lactate in 5% Sheep Blood Agar Plate. (Adults)					
Start Date: February 1980			Est. Term: Date: ---		
Principal Investigator:			Ability:		
LTC Charles L. Lamke, MS			DDEANC		
Dept/Svc: Pathology, Clinical Investigation			Associate Investigators:		
Key Words:			CPT Richard W. Harris, MS		
Accumulative MEDCASE		Est Accumulative		Periodic Not approved for continuation.	
Cost: None		OMA Cost: None		Review Results	
Study Objective: To compare the ability of sulfamethoxazole-trimethoprim in 5% sheep blood agar (SXT) and 5% sheep blood agar to isolate beta hemolytic streptococci.					

Technical Approach: Routine cultures submitted for throat culture were placed on both sets of media. All plates positive for gram positive catalase negative beta hemolytic cocci were identified by fluorescent antibody technique. An asymptomatic control group of blood donors was evaluated for carrier rates of group A streptococci.

Progress: The routine cultures and control groups have been completed. The SXT plates were significantly more effective in isolating group A streptococci than the routine blood agar.

Detail Summary Sheet

Date: 6 November 1980 Prot No.: 80-20 Status: Terminated.
 Title: Development of Selective Media for Legionella pneumophila.

Start Date:	Est Comp Date:
Principal Investigator:	Facility:
David Wall, DAC	DDEA/C
Dept/Svc: Pathology, Clinical Investigation	Associate Investigators:
	CPT Richard W. Harris, MSC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Not approved for continuation. Review Results

Study Objective: To evaluate and develop the use of a media to enhance the recovery rate of Legionella pneumophila from various biological sources.

Technical Approach: Develop and utilize enriched media to grow all of the various strains of Legionella sp. Develop and utilize that same enriched media with various broad spectrum antibiotics added which will not inhibit the growth of Legionella pneumophila. Use the media from #2 and verify its ability to inhibit the growth of various normal flora organisms and concomitantly support the growth of all strains of Legionella pneumophila.

Progress: Due to departure of principal investigator, this protocol was never started and thus is terminated.

Detail Summary Sheet

Date: 14 October 1980 Prot No.: 80-23 Status: Ongoing
 Title: Evaluation Study on Sulfamethoxazole-Trimethoprim Lactate in 5% Sheep
 Blood Agar Plate. (Children)

Start Date: Approx 20 October 1980		Est Comp Date: November 1980
Principal Investigator: LTJ Charles L. Lanke, MS Dept/Svc: Pathology, Clinical Investigation		Facility: CDEMMC Associate Investigators: CPT Richard W. Harris, MS
Key Words: Antibiotic Inhibition, Selective Media		
Accumulative MEDCASE Cost: None	Est Accumulative OMA Cost: None	Periodic Not reviewed. Review Results

Study Objective: To evaluate the percentage of beta hemolytic streptococci isolated from a normal pediatric population utilizing the standard procedures versus the use of the selective SXT media.

Technical Approach: Approximately 100 normal pediatric patients will be utilized in this study and the results will be evaluated.

Progress: None. Protocol approved late July 1980, there was not enough time to start project before end of FY 80.

Detail Summary Sheet

Date: 14 October 1980 Form No.: 79-26 Status: Ongoing
 Title: Family Practice Resident Surgical Instructional Experience.

Start Date: June 1979		Est. Date:
Principal Investigator: CPT Phillip W. Blair, MC		Facility: DDEAMC
Dept./Svc: Family Practice, Clinical Investigation		Associate Investigators: MAJ J. Bruce Arensman, VC
Key Words:		
Accumulative MEDCASE Cost: -	Est Accumulative OMA Cost: -	Periodic Approved for continuation. Review Results

Study Objective: To evaluate the benefits of trauma management training using animal models among Family Practice Residents.

Technical Approach: In an appropriately anesthetized animal several emergency procedures would be performed to gain skill and proficiency.

Cut down	Tracheotomies
Arterial lines	Thoracotomies
Peritoneal lavage	CVP placement

Expectations and evaluations of the course will be compared to individual experience levels.

Progress: This project is still attempting to gain support from curriculum supervisors of residency training. Ten residents have partially completed the course with poor to excellent ratings of it. The difficulty is in establishing time allocation for those residents involved, as well as gaining staff support.

Detail Summary Sheet

Date: 30 October 1980 Prot No.: 79-37 Status: Ongoing
 Title: Routine Use of Serum Uric Acid Levels at 36 Weeks Gestation as Screening Test for Preeclampsia as an Aid to Further Management.

Start Date: January 1980		Est Comp Date:
Principal Investigator:		Facility:
CPT Paul J. Martin, MD		DDEAMC
Dept/Svc: Family Practice		Associate Investigators:
Key Words:		CPT Ellis M. Knight, MD
Serum Uric Acid		
Preeclampsia		
Accumulative MEDCASE Cost: 0	Est Accumulative OMA Cost: 0	Periodic Approved for continuation. Review Results

Study Objective: To demonstrate that: A. Serum uric acid level is a simple specific screening test for preeclampsia at 36 weeks gestation; B. Its prognostic significance is great enough to warrant its use as a routine lab parameter in all pregnancies. To investigate effects of age and multiparity on serum urate levels.

Technical Approach: Seventy-six randomly selected pregnant women presenting for routine prenatal care at the DDEAMC Family Practice Clinic were included in this study. A serum SMA-18 screening chemistry analysis was drawn on each of these women at 36 weeks gestation. This screening profile included uric acid levels. After delivery a chart review was done on each patient and they were categorized into one of the following areas: uncomplicated pregnancy, gestational hypertension, preeclampsia, or severe preeclampsia.

Progress: Of the 76 patients initially presenting for study approximately three fourths of 43 patients' charts were obtainable for review. Of the 43 women, 16 were primigravidas and 27 were multigravidas. Among the primips the average uric acid level obtained was 4.2. The average uric acid level for multips was also 4.2. Two patients out of the 43 were diagnosed as preeclamptic and seemed to meet the criterion on chart review for this diagnosis. Several other patients carried this diagnosis on their charts but did not have documentation available to reliably confirm the diagnosis. Of the two patients carrying the diagnosis, the average uric acid obtained was 5.4. None patients appeared to meet the criterion for gestational hypertension. Their average uric acid level was 4.7. No patients met the diagnostic criteria for severe preeclampsia.

Detail Summary Sheet

Date: 14 October 1980 Prot No.: 79-17 Status: Ongoing
 Title: Incidence of PCP-Related Psychosis.

Start Date: August 1980		Est Comp Date:
Principal Investigator:		Facility:
MAJ Willie M. Patterson, MC		DDEAMC
Dept/Svc: Psychiatry & Neurology		Associate Investigators:
Key Words:		LTC William E. Logan, MC
Accumulative MEDCASE	Est Accumulative	Periodic Not reviewed.
Cost: -	OMA Cost: -	Review Results

Study Objective: To determine the incidence of exposure to PCP in patients admitted to the DDEAMC Inpatient Psychiatry Service and the incidence of PCP-related psychosis.

Technical Approach: Urine screen for PCP on all patients admitted over a four month period (approximately 200 cases).

Progress: Data has been accumulated. Incidence extremely low, much lower than reported elsewhere. It is possible that the analytic method used for PCP at DDEAMC may miss 80% of positives. Study currently on "hold" status.

Detail Summary Sheet

Date: 9 October 1980 Report No.: 80-10 Status: Ongoing
 Title: Investigation of Patient Non-Compliance: Failure to Claim Turned-In
 Cost-Free Prescriptions.

Start Date: March 1980	Est. Date: January 1981
Principal Investigator: MAJ William S. Russell, MC	EDENEC
Dept/Svc: Psychiatry & Neurology, Clinical Investigation/Pharmacy	Associate Investigators: MAJ Willie Patterson, MC LTC Andree J. Lloyd, MS LTC Sam Shannon, Jr, MS
Key Words:	

Accumulative MEDCASE Cost: -	Est Accumulative OMA Cost: -	Periodic Not reviewed. Review Results
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Study Objective: The explication of those factors important in the etiology of patient non-compliance in a cost-free health care system.

Technical Approach: This study utilized a unique population of patients known to be 100% non-compliant with their prescribed medical regimen. This non-compliance was unrelated to cost to the individual. Data was gathered via questionnaire on factors which might have contributed to this non-compliance. The doctor-patient relationship was an area of particular focus. A list of patients who failed to pick up turned-in prescriptions was compiled by the Pharmacy for March, April and May 1980. These individuals, along with a control sample who did pick up prescriptions during the same time frame, were mailed questionnaires and return envelopes.

Progress: The data gathering has been completed. Statistical analysis is currently being done.

Detail Summary Sheet

Date: 9 October 1980		Prot No.: 80-11	Status: Ongoing
Title: Increasing Hypertensive Regimen Compliance by Teaching Doctor-Patient Negotiations.			
Start Date: January 1981		Est Comp Date: January 1982	
Principal Investigator:		Facility:	
MAJ William G. Bissell, MC		DDEAMC	
Dept/Svc: Psychiatry & Neurology, Clinical Investigation		Associate Investigators:	
Key Words:		MAJ Willie Patterson, MC CPT Gregory D. Aeschliman, MC LTC Andree J. Lloyd, MS	
Accumulative MEDCASE	Est Accumulative	Periodic Not reviewed.	
Cost: -	OMA Cost: -	Review Results	

Study Objective: The objective is to attempt to develop a cost-effective method of improving hypertensive regimen compliance by utilizing a videotape presentation to teach both doctors and patients better methods of communication.

Technical Approach: A videotape has been produced that shows typical doctor-patient interactions and then specific ways in which the doctor and the patient can facilitate better communications. This tape will be shown to groups of Family Practice patients who are being treated for hypertension and to their Family Practice physicians. Some groups will have a group discussion after the film, others will not. Together with control groups, a three by three study will be done with nine groups of patients. Parameters such as systolic and diastolic B.P., body weight, and amount of medication will be analyzed for all groups.

Progress: The videotape has been completed. Retrospective study of the patients' charts will begin soon. The prospective portion of the study will begin in Jan 81.

Detail Summary Sheet

Date: 9 October 1980 Prot No.: 80-12 Status: Ongoing
 Title: Development of a Scale to Predict Trainee Failure in the Army.

Start Date: November 1980	Est Comp Date: June 1981
Principal Investigator: MAJ William G. Bissell, MC	Facility: DDEAMC
Dept/Svc: Psychiatry & Neurology, Clinical Investigation	Associate Investigators: CPT Robin Hostetter, MC MAJ Willie Patterson, MC LTC Andree J. Lloyd, MS
Key Words:	
Accumulative MEDCASE Cost: -	Est Accumulative OMA Cost: -
	Periodic Not reviewed. Review Results

Study Objective: To develop a cost-effective easily administered screening examination to identify those trainees who will subsequently not be able to complete training due to emotional immaturity.

Technical Approach: A set of 148 questions has been developed which assesses specific ego functions which are necessary to successfully complete military training. Deviation from normal scores is hypothesized to be predictive of subsequent failure.

Progress: The questionnaire has been developed and the methodology for collecting the data and analyzing it via HSC computer support has been worked out. Administration of the questionnaires should begin in October 1980.

Detail Summary Sheet

Date: 29 October 1980		Prot No.: 80-19		Status: Ongoing	
Title: Pain Relief and Return of Function Following Surgery: A Comparison of Predictors.					
Start Date: January 1980			Est Comp Date: September 1981		
Principal Investigator:			Facility:		
LTC John J. Treanor, MC			DDEAMC		
Dept/Svc: Psychiatry & Neurology			Associate Investigators:		
Key Words:			LTC John McCormack, MC		
			LTC Andree J. Lloyd, MSC		
			LTC Walter Piskun, MC		
Accumulative MEDCASE Cost: 0		Est Accumulative OMA Cost:		Periodic Approved for continuation. Review Results	

Study Objective: To compare selected predictors of outcome of neurosurgical intervention for relief of low back pain (LBP).

Technical Approach: Candidates for surgery will be evaluated by the principal investigator prior to surgery. This evaluation will consist of an anamnestic history, mental status exam, and the HENDLER SCREENING TEST with minor modifications for military personnel. The MMPI and Beck Depression Index will be evaluated pre-operatively by the Chief of Psychology, DDEAMC. The operating surgeon will provide a weighted scale based on pre-operative physical findings, EMG and myelogram as well as a description of operative findings. A simple questionnaire will be administered by the principal investigator approximately six months after surgery to evaluate relief of pain and/or return of function.

Progress: During the period Jan thru Jul 80, 31 cases completed pre-surgery testing. Post-operative evaluations have been initiated on 11 of these cases. Data so far is not indicative of any discernable trend. Departure of Dr. Piskun (Neurosurgeon) created an hiatus of new cases during the last two months. It is anticipated that this will be corrected when the new neurosurgeon is established.

Detail Summary Sheet

Date: 28 October 1980 Prot No.: 80-24 Status: Ongoing
 Title: Modification of Attitudes Toward Women in the Army/The Male-Female Soldier Team.

Start Date: 14 July 1980	Est Comp Date: 30 December 1980
Principal Investigator: CPT Victor C. Bell, MC	Facility: DDEAMC
Dept/Svc: Psychiatry & Neurology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost: 0	Est Accumulative OMA Cost: \$130.00
	Periodic Not reviewed. Review Results

Study Objective: To measure effect of small-group activities in leadership training with a focus on male-female relationships to attitudinal change concerning the role of males and females in the US Army.

Technical Approach: Groups of NCO's in 3d, 5th, 6th Bns, 1st STB, have been formed consisting of 6 to 8 members each; and are actively engaged in weekly sessions.

Progress: The above groups are actively discussing the male-female issue. NCO's have established and led groups of trainees weekly and discussed their progress in the NCO group.

Detail Summary Sheet

Date: 9 October 1980		Prot No.: 80-25		Status: Ongoing	
Title: Efficacy of Triavil for Relief of Chronic Low Back Pain: A Double-Blind Study.					
Start Date: November 1980			Est Comp Date: April 1981		
Principal Investigator:			Facility:		
CPT Gary M. Bings, MC			DDEAMC		
Dept/Svc: Psychiatry & Neurology, Clinical Investigation			Associate Investigators:		
Key Words:			COL John J. Treanor, MC		
			MAJ William G. Bissell, MC		
			CPT Charles J. Hannan, Jr., MS		
Accumulative MEDCASE		Est Accumulative		Periodic Not reviewed.	
Cost: -		OMA Cost: -		Review Results	
Study Objective: To assess efficacy of Triavil for relief of chronic low back pain.					

Technical Approach: Double-blind, double-crossover study using Triavil and placebo in approximately 20-25 patients.

Progress: Presently have made arrangements for preparation of placebo and have list of patients from previous study (with low back pain) to contact. Will begin contacting patients soon with anticipated starting date of 1 November 1980.

*Implementation suspended pending TSGO approval.

Detail Summary Sheet

Date: 17 November 1980 Prot No.: 80-27 Status: Ongoing
 Title: Study of Herpes Simplex Virus I Antibodies in Recently Admitted Psychiatric Patients.

Start Date:		Est Comp Date:
Principal Investigator:		Facility:
LTC Matthew E. Levine, MC		DDEAMC
Dept/Svc: Psychiatry, Pathology		Associate Investigators:
Key Words:		Mr. Paul Trainor, DAC
Accumulative MEDCASE Cost: -	Est Accumulative OMA Cost: -	Periodic Review Results Not Reviewed.

Study Objective: To obtain serum antibody titers to Herpes Simplex Virus I of psychiatric inpatients for comparison to non-psychiatric serum levels and correlation to various psychiatric diagnostic parameters.

Technical Approach: All patients admitted to the psychiatric wards (3 wards with a bed capacity of 100, and an average daily census of 73.6) of the DDEAMC will be screened for the presence of antibodies to HSV-I virus. Screening will be done by means of the Indirect Fluorescent Antibody Test at dilutions of 1:8 and 1:32, and further if antibody is found to be present.

Progress: Local approval in September 1980, insufficient time for implementation this fiscal year.

Detail Summary Sheet

Date: 14 October 1980		Prot No.: 80-22	Status: Completed
Title: A Comparison of Teacher Presentation and Audiovisual Methods of Giving Postpartum Infant Care Classes.			
Start Date: 9 June 1980		Est Comp Date: 30 August 1980	
Principal Investigator:		Funding:	
CPT Judith A. Reynolds, AMC		DDEAMC	
Dept/svc: Nursing		Associate Investigators:	
Key Words:			
Accumulative MEDCASE Cost: -	Est Accumulative OMA Cost: -	Periodic Not approved for continuous Review Results tion.	

Study Objective: To examine whether an audiovisual method for teaching infant care information to new mothers in the immediate postpartum period was more effective than the current teacher method. This was measured in terms of the knowledge on infant care these mothers obtained, as measured by post-test questionnaire.

Technical Approach: The data was gathered over an eight week period. The audio-visual and teacher presentation methods of giving infant care information were used on alternate weeks. Each morning a nursery staff member determined subject eligibility, and as subjects were selected administered to them the post-test questionnaire.

Progress: Thirty-one questionnaires were collected, 22 from the audiovisual group and nine from the teacher presentation group. Of the demographic data, day of giving the class, method used, there was no significant correlation with the overall scores except in relation to age. Pearson Correlation Coefficients indicated that age correlated significantly with the total score at the .05 level. However, an analysis of variance showed no significant age difference in the mean age of the two groups. This information suggests that use of the audiovisual to reduce staff time involved in teaching infant care information to postpartum mothers could be implemented without significantly changing the amount of information the mothers obtained.

Detail Summary Sheet

Date: 15 October 1980 Prot No.: 80-26 Status: Ongoing
 Title: Enhancement of Bonding by Formal Childbirth Preparation.

Start Date: 1 August 1980		Est Comp Date: 1 November 1980
Principal Investigator: CPT Jane H. Ingham, MNC		Facility: DOEAMC
Dept/Svc: Nursing		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost: None	Est Accumulative OMA Cost: None	Periodic Not reviewed. Review Results

Study Objective: To determine if there is a difference in the bonding capabilities of mothers who attended childbirth classes vs mothers who did not.

Technical Approach: Observation of first-time mothers during the feeding hour. The time spend with each mother before the observation is about 30 minutes to one hours. Then the mothers are observed and according to the scale, scores are given on their bonding behavior towards their babies.

Progress: The progress is slow since the maternity cases per month of first-time mothers, without complications, and married, are few. Total observed to date are four mothers who have not attended classes and three who have. Five of each are needed. Expect to complete study by 1 November 1980.

Detail Summary Sheet

Date: 18 November 1980 Prot No.: 80-32 Status: Ongoing
 Title: The Effect of Specific Instructional Objectives on Student's Retention.

Start Date: October 1980		Est Comp Date: December 1981
Principal Investigator: Mr Lawrence J. Eberlin, MNC		Facility: DDEAMC
Dept/Svc: Nursing		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost: -	Est Accumulative OMA Cost: -	Periodic Review Results Not reviewed.

Study Objective: To investigate the benefits of informing students of the instructional objectives. Since there seems to be conflicting evidence concerning all aspects of behavioral objectives, it was decided to restrict this investigation to a basic question, namely, will behavioral objectives help to improve the students' retention?

Technical Approach: Subjects will be students enrolled in the Patient Care Specialist Course at DDEAMC. One class will be the control group, the following class will be the experimental group. Control group will receive a list of specific instructional objectives for the subject matter, the experimental group will not be given the list of objectives. Both groups will receive the same 23 hours of lecture. A comprehensive, objective type test will be given 12 weeks after the completion of the subject matter. This test will be used to evaluate the students' retention.

Progress: Local approval in September 1980, insufficient time for implementation in fiscal year 1980.

Detail Summary Sheet

Date: 18 November 1980 Prot No.: 80-33 Status: Ongoing
 Title: Touch in Nursing: Relationship of Values to Selected Characteristics in Nurses.

Start Date: October 1980		Est Comp Date: November 1980
Principal Investigator: Jimmie R. Williams, R.N., B.S.N.		Facility: DDEAMC
Dept/Svc: Nursing		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost: -	Est Accumulative OMA Cost: -	Periodic Review Results Not reviewed.

Study Objective: To acquire additional information in the possible meanings of touch to different individuals and how touch may be used most effectively as a separate nursing care measure.

Technical Approach: The investigator will conduct each interview using the "Interview Schedule, Use of Touch" developed for this study. Forty military registered nurses currently working at DDEAMC will be interviewed. Subjects will be between the ages of 22-35 years, be native born USA citizens, have completed a minimum of a baccalaureate degree in nursing, and have a minimum of two years military nursing experience. These 40 nurses will be divided into two equal groups of twenty male and twenty female nurses.

Progress: Local approval in September 1980, insufficient time for implementation in fiscal year 1980.

Detail Summary Sheet

Date: 30 October 1980 Prot No.: 80-17 Status: Ongoing
 Title: The Prophylactic Use of Doxycycline and Cephmandole in Women Undergoing Vaginal Hysterectomy.

Start Date: February 1980		Est Comp Date:
Principal Investigator:		Facility:
LTC Gary D. Breachan, DC, MC		DDEAMC
Dept/Svc: Obstetrics-Gynecology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost: 0	Est Accumulative OMA Cost: 0	Periodic Review Results
Approved for continuation.		

Study Objective: To compare the efficacy of prophylactic doxycycline or cephamandole in reducing the incidence and severity of postoperative infectious morbidity in pre-menopausal women undergoing vaginal hysterectomy.

Technical Approach: A prospective randomized, comparative, third-party blinded in pharmacy study is being conducted on all patients undergoing vaginal hysterectomy between February 1980 and December 1980.

Progress: The study is progressing well. There have been no complications or adverse reactions related to either drug used in the study. Thus far, 30 patients have been enrolled in the study.

Detail Summary Sheet

Date: 6 November 1980 Prot No.: 79-12 Status: Terminated
 Title: Bullet Size Determination by Use of X-rays.

Start Date:		Est. Comp. Date:
Principal Investigator: George E. Peters, DAC		Facility: DDEAMC
Dept/Svc: Radiology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine if the theory of x-rays and angulation as proposed will yield the same or comparable results when done under actual conditions to determine bullet caliber size in a patient.

Technical Approach: To determine the precise depth location and exact dimensions of a foreign object or lesion in a patient. Forensic application, if this technique is validated, could be most valuable to definitively establish bullet caliber in assault victims in whom the bullet has not or cannot be removed. Under general endotracheal anesthesia, different caliber bullets will be acutely implanted in (8 mixed mongrel) dogs and x-rays will be made to determine if the determination of caliber size can be made under actual conditions using calibrated standard bullets, radiographic scale and angulations. This will involve that all bullet sizes can be determined since shapes and sizes are often destroyed by the force of impact. Determination will be made by implanting bullets to determine their depth. Animals will be terminated at the end of each experiment. Data will be analyzed by comparing the results of the implanted bullets as measured, using the calibrated techniques, by a radiologist (double-blind) with the actual known bullet caliber.

Progress: Due to non-activity, this protocol is terminated.

Detail Summary Sheet

Date: 15 October 1980		Ref No: 79-29	Status: Ongoing
Title: Tissue Reaction in the Oral Mucosa to Surgical Silk Suture, Synthetic Polyester Fiber Suture, and Monofilament Suture.			
Start Date: July 1979		Last Date:	
Principal Investigator:		Sponsor:	
COL E.J. Neaverth, DC		DDEAMC	
Subject: Dental Activity, Clinical Investigation		Associate Investigators:	
Key Words:			
Accumulative MEDCASE Cost: -	Est Accumulative OMA Cost: -	Periodic Approved for continuation. Review Results	
Study Objective: To study the tissue reaction in oral mucosa to various suture materials.			

Technical Approach: Mersiline, silk, nylon sutures were placed in the oral mucosa of four dogs.

Progress: The clinical approach has been completed on four dogs. Histological evaluation has been delayed for technical reasons.

Detail Summary Sheet

Date: 10 November 1980 Prot No.: 78-35 Status: Ongoing
 Title: General Dentistry Resident Surgical Instructional Experience - Development and Implementation of a Program.

Start Date: November 1978		Est Comp Date:
Principal Investigator:		Facility:
DCL William R. Schriker, DC		DDEAMC
Dept/Svc: Dental Activity, Clinical Investigation		Associate Investigators:
Key Words:		MAJ J. Bruce Arensman, VC
Accumulative MEDCASE Cost: -	Est Accumulative OMA Cost: -	Periodic Approved for continuation. Review Results

Study Objective: 1) To develop and implement an audiovisual and practical training program involving surgical instrumentation, suture materials, sterile technique, anesthesia and surgery for the General Dentistry Residents. 2) To provide a meaningful, highly structured course of direct surgical and anesthesia experience in Clinical Investigation Laboratories.

Technical Approach: Through the use of didactic and hands-on instruction techniques, a program of instruction is to be developed implementing the above objective.

Progress: Nine 3-hour sessions were conducted during this past fiscal year. Sterile technique, suturing, hemostasis, wound debridment, venous cutdown, and cricothyroidotomy were some of the techniques taught. No audiovisual materials have been developed.

Detail Summary Sheet

Date: 6 November 1980		Prot No.: 80-3	Status: Ongoing
Title: Penetration of Topically Applied Carbon 14 Tagged 2% Lidocaine on Dog Oral Mucosa.			
Start Date: February 1980		Est Comp Date: December 1982	
Principal Investigator: CPT Andrew Chandler, DC		Facility: DDEAMC	
Dept/Svc: Dental Activity, Clinical Investigation		Associate Investigators: CPT Charles J. Hannan, Jr., PhD, MSC James C. McPherson, III, PhD, DAC	
Key Words: Lidocaine Adsorption			
Accumulative MEDCASE Cost: -	Est Accumulative OMA Cost: -	Periodic Approved for continuation. Review Results	

Study Objective: Topically applied local anesthetics are used to relieve pain from ulcers and wounds, to anesthetize mucosa prior to injection and to inhibit a gag reflex. These agents can be administered as ointments, gels, solutions, pastes and sprays. The chemical and physical form in which these agents are administered, along with the method of administration affect their adsorption. In dentistry, it would be important to minimize the effect of pain due to injection or other dental procedures by maximizing the effectiveness of these agents. This study was undertaken to study the penetration and adsorption of Lidocaine jelly in the oral mucosa of dogs. Technical Approach: Carbon-14 labeled Lidocaine HCl was added to a 2% Lidocaine-HCl jelly. This mixture was applied to the oral mucosa in each experimental site (one in each quadrant of the mouth) using a retaining 10mmx6mm wire template. After appropriate time intervals, the template was removed, the templated area swabbed three times with ethanol moistened gauze sponges and two 3mm punch biopsies taken. Appropriate control biopsies were taken in adjacent areas not receiving the Lidocaine agent. The tissue samples were solublized and counted in a liquid scintillation counter.

Progress: The initial phase of the project has been completed. A number of technical problems and mechanical delays were encountered. A number of new techniques and procedures had to be worked out to perform the experiment. The preliminary data suggests that the initial penetration of Carbon-14 labeled Lidocaine-HCl is very rapid and its rate of penetration may be markedly affected by such simple procedures as wiping the oral mucosa with a gauze sponge or removing the outer layer of oral mucosa with a piece of non-sticking surgical tape. The completion of this residency research project was seriously hampered by the lack of an operational liquid scintillation counter.

Detail Summary Sheet

Date: 15 October 1980		Prot No.: 80-6		Status: Completed	
Title: A Study of Tissue Response to Two Types of Sutures as Related to Time.					
Start Date: February 1980			Est Comp Date: June 1980		
Principal Investigator:			Facility:		
CPT Mark S. Ritz, DC			DDEAMC		
Dept/Svc: Dental Activity, Clinical			Associate Investigators:		
Investigation			COL Elmer J. Neaverth, DC		
Key Words:					
Accumulative MEDCASE		Est Accumulative		Periodic Not approved for continuation.	
Cost: -		OMA Cost: -		Review Results	
Study Objective: To study the tissue response to two types of suture material.					

Technical Approach: Using non-capillary silk and monofilament suture placed in dog maxillary and mandibular, gingival tissue at four intervals over six days. Histologic evaluation of suture reaction was made.

Progress: The methods and technical approach were found to be lacking with regards to the model because of the many variables which were difficult to control. As a result an analysis of the histological data could only show general trends and nothing concrete. Histologically, there was little difference in tissue reaction to silk and nylon. However, there was a trend for tissue reaction to increase with the length of time the sutures were present in the tissue. Observation suggests that the early removal of sutures may be of clinical importance for early wound healing. The results of the histologic and clinical evaluations were submitted as part of a thesis requirement by CPT Mark Ritz, DC.

Detail Summary Sheet

Date: 15 October 1980 Prot No.: 79-25 Status: Ongoing
 Title: The Effect of Guaifenesin in the Treatment of Middle Ear Effusion: A Double Blind Study.

Start Date: November 1980		Est Comp Date:
Principal Investigator:		Location: Martin Army Hospital
CPT Gregory W. Blake, MC		Fort Benning, GA
Dept/Svc: Family Practice		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost: -	Est Accumulative OMA Cost: -	Periodic Not reviewed. Review Results

Study Objective: To determine whether guaifenesin, a mucolytic agent has a place in the management of middle ear effusion.

Technical Approach: The study is a double blind protocol looking at children aged 2 - 16 years who have middle ear effusion. Middle ear effusion is diagnosed by clinical history, otoscopic exam, and audiology evaluation. Audiologic criteria are a Type B tympanogram or two of the following: a difference between air and bone conduction hearing threshold level of .15 dB or more on three test frequencies; a maximum compliance change peak which is negatively displaced 100 mm or more from ambient air; and a static middle ear compliance less than 0.26 ml. Half of those patients agreeing to enter the study will be given guaifenesin and the other half the base of guaifenesin. Patients will be followed for clinical and audiologic improvement at two and four weeks.

Progress: Study currently being set up at Fort Benning. Approval not received in time to start during Fort Gordon tenure.

Detail Summary Sheet

Date: 17 November 1980	Prot No.: 80-31	Status: Ongoing
Title: Medical Screen and Functional Testing in a Pilot Cohort of Over Age Forty Active Duty Army Personnel to be Trained and Tested in the New Army "Over Forty Physical Training Program".		
Start Date: October 1980	Est Comp Date: May 1981	
Principal Investigator: CPT Ronald Albright, MC	Facility: USAMEDDAC, Ft Benning, GA	
Dept/Svc: Medicine	Associate Investigators:	
Key Words:		
Accumulative MEDCASE Cost: -	Est Accumulative OMA Cost: -	Periodic Review Results Not reviewed.

Study Objective: The purpose of this protocol is to attempt to identify latent coronary artery disease (CAD) in asymptomatic active duty military personnel prior to conditioning training. Multiple serial screening procedures will be used to ascertain the safety of aerobic testing/training in individuals over forty years of age regardless of their initial state of conditioning.

Technical Approach: The strategy proposed is to validate existing screening tests that have been applied to other groups of military personnel. A pilot group will be tested relatively intensively with the intent of identifying the combination of screening procedures having the sensitivity, specificity and predictive value necessary to identify a subgroup of individuals at increased risk of cardiac disorders requiring definitive evaluation. A serial screening strategy will be tested as to its sensitivity, specificity, and predictive value. Projections can then be made for the materiel and personnel costs required for an Army-wide screening program prior to cardiovascular fitness testing of all active duty members over age forty.

Progress: Local approval in September 1980, insufficient time for implementation this fiscal year.

Detail Summary Sheet

Date: 17 October 1980 Prot No.: 78-14 Status: Ongoing
 Title: Intraocular Lens Study.

Start Date: May 1978		Est Comp Date:
Principal Investigator: COL William T. Spelsberg, MC		Facility: DDEAMC and US Lyster Army Hospital, Ft Eucker, AL
Dept/Svc: Surgery/Ophthalmology		Associate Investigators: COL Nicholas Barreca, MC
Key Words: Intraocular Lens, Implant, Ophthalmology, Aphakia, Surgery.		
Accumulative MEDCASE Cost: 0	Est Accumulative OMA Cost: \$3,000	Periodic Approved for continuation. Review Results
Study Objective: Implantation of intraocular lenses in accordance with previously established FDA protocol.		

Technical Approach: Currently accepted surgical techniques for cataract extraction
and intraocular lens implantation using the operating microscope.

Progress: At time of report no individual had been entered into study at DDEAMC.
 US Lyster Army Hospital: The first patients to be implanted under this study
 are scheduled for surgery on 27 October 1980. Funding requirements for FY 80
 have been expended and consist of the stockage of intraocular lenses.

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